

**REMARKS**

Applicants have amended claims 1, 7, 15, 16, 18, and 24 as set forth above. No new matter has been added by way of these amendments. In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The Office has rejected claims 1-5, 7-11, 13, 16, 18-22, and 24-29 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,494,863 to Shaw (“Shaw”) in view of U.S. Patent No. 5,084,017 to Maffetone (“Maffetone”) and claims 6, 14, 15, 23, and 30 under 35 U.S.C. § 103(a) as being unpatentable over Shaw in view of Maffetone in view of UK Patent Application No. GB 2203047 to Banks (“Banks”).

The Office asserts Shaw discloses a disabling system for a syringe (Figures 15-19) comprising a plunger (handle 116) having a plurality of aligned steps (stepped serrations 124) disposed longitudinally along the plunger (Figure 15) and a collar (clip structure 114 and collar 126) mountable to the barrel (Figure 15), said collar comprising an inner member (collar 126) and an outer member (clip 114; Figure 16) having pawls (teeth 136) capable of engaging the ratchets of the plunger (Figure 18), said inner member operable to prevent engagement of the ratchets by the pawls (Figures 15, 17) until the plunger is depressed (col. 12, lines 8-20).

The Office acknowledges Shaw does not disclose the inner member comprising one or more projections to prevent initial engagement of the ratchet by the at least one pawl until the plunger is depressed, but asserts Maffetone discloses a projection (guide pin, 85) to prevent initial engagement of the ratchet by the at least one pawl until the plunger is depressed (Figures 19-21). The Office states that at the time of invention, it would have been obvious to one of ordinary skill in the art to modify the device of Shaw with the projection (guide pin, 85) of Maffetone to prevent premature movement of the actuating rod into the solution dispensing mode (Column 7, lines 38-50).

Finally, the Office acknowledges that Shaw in view of Maffetone does not disclose the projection (guide pin, 85) being resiliently deformable. The Office, however, asserts that it would have been an obvious matter of design choice to have the projection be resiliently deformable, since applicant has not disclosed that the deformability of the projection solves any

stated problem or is for any particular purpose and it appears that the invention would perform equally well with the stationary projection preventing premature movement of the actuating rod taught by Maffetone. The Office further asserts that the Applicant states twice in the specification that the projection is “resiliently deformable,” but never states that its deformability solves any stated problem.

In reference to claims 5, 13, 22, and 29, the Office references the device of claims 1, 18, and 28 above wherein the inner and outer member are incapable of rotation relative to each other (citing Shaw at col. 11, lines 39-42, wherein the outer member – clip 114 – is in a fixed position relative to the barrel and therefore would be incapable of rotation relative to the inner member).

In reference to claim 16, the Office states that Shaw discloses a method of using a syringe comprising: providing a syringe comprising a plunger (handle 116) including at least one ratchet (serrations 124), a barrel (barrel 12) and a collar (clip 114 and collar 126), said collar comprising an inner member (collar 126) and outer member (clip 114) having at least one pawl (teeth 136); and depressing the plunger from a first position (Figure 15) at which the pawl is not engageable with the ratchet by at least one projection (catch 128) of the inner member positioned between the pawl and ratchet (Figure 15) to a second position (Figure 18) at which the pawl is engaged with the ratchet to prevent plunger withdrawal (Figure 18; col. 12, lines 27-34, wherein it is impossible to pull the handle 116 backwards when it is in the defined second position of Figure 18).

The Office again acknowledges that Shaw does not disclose the inner member comprising one or more projections to prevent initial engagement of the ratchet by the at least one pawl until the plunger is depressed. Maffetone discloses a projection (guide pin, 85) to prevent initial engagement of the ratchet by the at least one pawl until the plunger is depressed (Figures 19-21). The Office concludes that at the time of invention, it would have been obvious to one of ordinary skill in the art to modify the device of Shaw with the projection (guide pin, 85) of Maffetone to prevent premature movement of the actuating rod into the solution dispensing mode (Column 7, lines 38-50).

The Office notes that Shaw in view of Maffetone does not disclose the projection (guide pin, 85) being resiliently deformable, but states that it would have been an obvious matter of design choice to have the projection be resiliently deformable, since applicant has not disclosed that the deformability of the projection solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the stationary projection preventing premature movement of the actuating rod taught by Maffetone. Finally, the Office asserts in particular that Applicant states twice in the specification that the projection is “resiliently deformable” but never states that its deformability solves any stated problem.

The Applicants understand the Office’s interpretation of Shaw and Maffetone to concede the absence of a resiliently deformable projection, *e.g.*, Maffetone’s guide pin 85, but the Office then asserts that the specification doesn’t state the problem solved by or the purpose of the resiliently deformable projections. The Office concludes the incorporation of resiliently deformable projections is just a matter of “obvious design choice.”

Regarding the second set of rejections, Shaw in view of Maffetone in view of Banks in reference to claims 6, 14, 23, and 30, the Office states that Shaw discloses the device of claims 5, 13, 22, and 29 but fails to teach two fingers on the outer member that are capable of engaging guide slots on the plunger. Further, the Office states that Banks teaches a syringe comprising a plunger 4 that has splines 7-10 that lock into guide channels 11-14 in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

Moreover, the Office states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Shaw to have guide channels on the handle 116 and splines on the clip 114 as taught by Banks in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

In reference to claim 15, the Office states that Shaw teaches a syringe comprising a barrel (barrel 12) that comprises two pawls (fingers 136; Figure 15); and a plunger (handle 116) comprising: two opposed ratchets (serrations 124) engageable by the two pawls (Figure 18) to prevent withdrawal of the plunger during or following depression of the plunger (col. 12, lines 27-34); wherein the barrel comprises a collar (clip 114 and collar 126) having an inner member

(collar 126) operable to prevent engagement of the ratchet and pawls (Figure 15), the outer member (clip 114) comprising the two pawls (Figure 16). The Office acknowledges that Shaw fails to teach two fingers on the outer member that are capable of engaging guide slots on the plunger. However, the Office states that Banks teaches a syringe comprising a plunger 4 that has splines 7-10 that lock into guide channels 11 – 14 in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

The Office asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Shaw to have guide channels on the handle 116 and splines on the clip 114 as taught by Banks in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1- 6).

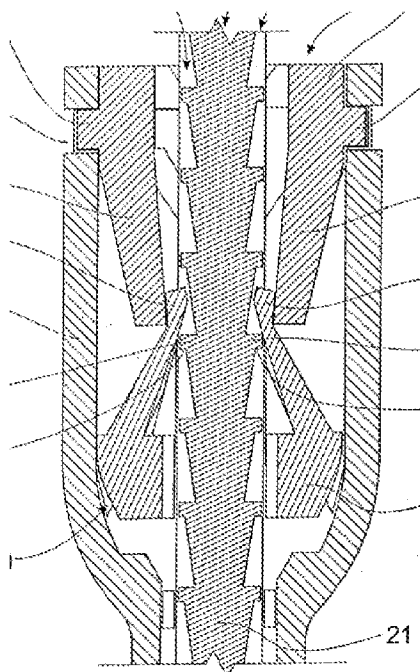
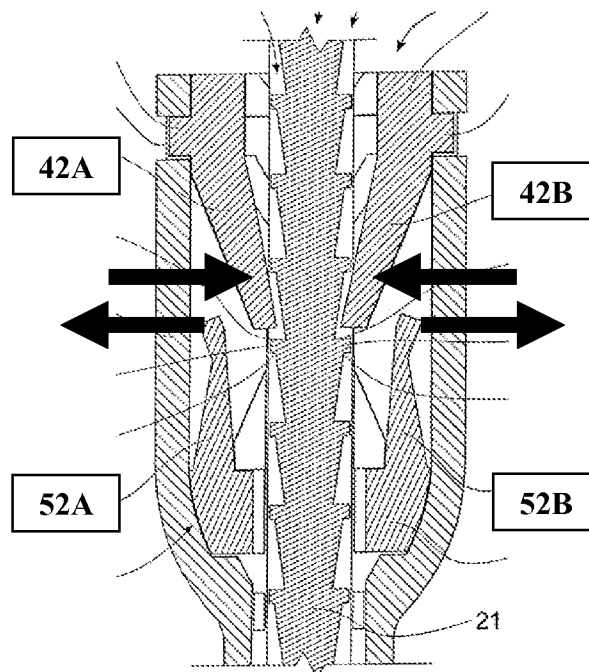
The references cited, Shaw, Maffetone, and Banks, either alone or in combination, do not disclose or suggest “resiliently deformable projections initially positioned between the pawl of the outer member and the ratchet to prevent engagement of the at least one ratchet by the at least one pawl until the plunger is depressed in the barrel forcing the inner member out of engagement with the outer member to allow the pawl of the outer member to engage the ratchet” as recited by claims 1, 7, 15, 16, 18, and 24.

The Office’s attention is respectfully directed to the specification, which explains the function and purpose of the resiliently deformable projections and the problem solved. First, it is necessary to appreciate the resilient deformability of the first and second projections 52A, 52B in the context of the pawls 42A, 42B, which are also resiliently deformable. The specification states, “[r]eferring now to FIG 3, outer member 40 comprises outer member body 41 having pawls 42A, 42B, channels 43A, 43B, fingers 44A, 44B and barrel-engaging shoulders 45A, 45B. Pawls 42A, 42B are resiliently deformable from an *initial* position where engagement with steps 24 is prevented *to a position* where pawls 42A, 42B can engage steps 24 to prevent, impede or otherwise hinder subsequent plunger 20 withdrawal, as will be described in more detail hereinafter.” (See p. 4, lines 25-30)(emphasis added).

The solid arrows in FIG. 4 of the present application shows that first and second projections 52A, 52B must be capable of a deformable, inward movement when pawls 42A, 42B of outer member 40 exert an inward pressure on the projections, whereby the projections stop the

pawls initially engaging the plunger ratchets. (*See* p. 5, lines 13-21 and FIG. 5, 6). To exert the described “inward pressure,” the projections must be elastically deformed from an initial at-rest position, such that the resiliency of the projections that tends to bring the deformed projections back to their initial position exerts the described pressure. “As can be seen in FIG 4, inner member 50 comprises inner member body 51 having first projection 52A and second projection 52B, which projections are resiliently deformable in the direction indicated by arrows.” (*See* p. 5, lines 1-3).

Further, the specification states that “[i]n this correctly aligned and non-rotatable configuration, first projection 52A and second projection 52B of inner member 50 are initially, respectively positioned between pawls 42A, 42B of outer member 40 and ratchets 23A, 23B, thereby preventing pawls 42A, 42B of collar 40 contacting steps 24A, 24B . . . thereby clamping projections 52A, 52B in position.” (*See* p. 5, lines 13-16). As described at page 5 line 26 to page 6 line 2, following plunger withdrawal upon depression of plunger 20, projections 52A, 52B are forced out of engagement with pawls 42A, 42B to thereby allow the pawls to engage the plunger ratchet and prevent the plunger being withdrawn (*e.g.* to refill the syringe). The projections must be sufficiently resilient to “snap back” into a position clear of the plunger and pawls, as seen in FIG. 6, and shown below. Likewise, the pawls 42A, 42B must also be sufficiently resilient to “snap back” into position and interfere with the steps 24A, 24B. The sections of FIG. 5 and FIG. 6 below show the movement of the projections 52A, 52B and the pawls 42A, 42B after the mutual interference is removed.

**FIG. 5****FIG. 6**

Figures 5 and 6 reproduced above, show the initial deformation of the projections and pawls, and the resilient projections returning to their original position. Thus, the purpose of the resiliently deformable projections is to cooperate with the resiliently deformable pawls so that:

- (i) initially the projections prevent the pawls from engaging the plunger ratchet during withdrawal of the plunger, at which point the projections are in a “deformed” position (FIG. 4; FIG. 5, reproduced above); and
- (ii) during plunger depression, the projections are forced out of engagement with the pawls and resiliently move back to a “non-deformed” position clear of the pawls (FIG. 6, reproduced above).

The problem addressed is that the plunger must be free to be withdrawn for filling and depressed for fluid delivery, while preventing further withdrawal after depression has started during fluid delivery. To do this, pawls are provided to engage the plunger ratchet and prevent withdrawal of the plunger only after plunger depression starts, but the further problem arose as to how to prevent the pawls engaging the ratchet when filling the syringe while allowing the pawls to engage the ratchet to prevent subsequent withdrawal. At least part of the solution was to provide resiliently deformable projections capable of adopting an initial position (i) outlined

above, and returning to a final position (ii). Respectfully, this is a non-obvious solution to the problem which is not a mere “obvious design choice” and which is clear from a reading of the specification and figures.

In contrast, the Maffetone guide pin 85 is incapable of performing this resilient deformable function because the Maffetone guide pin 85 is stationary (see column 3 line 43; column 5 line 22 and line 37; column 7 line 42). Maffetone does not teach, suggest, or describe the guide pin 85 moving in any way. Rather, the plunger is rotated to move the guide pin from guide track A to guide track B. There is nothing in Shaw or Maffetone to suggest that it would be obvious to use a pair of resiliently deformable projections to adopt two different positions relative to the pawls to initially block the pawls from engaging the plunger ratchet and subsequently allow the pawls to engage the plunger ratchet only after the plunger depression has started.

Finally, in light of the discussion provided, it should be clear that the Office’s comment that “it appears that the invention would perform equally well with the stationary projection preventing premature movement of the actuating rod taught by Maffetone,” (Office Action, p. 5), is incorrect since a stationary projection would not “snap back” into a position clear of the plunger and pawls, as seen in FIG. 6.

The addition of Banks does not resolve the deficiencies of Shaw and Maffetone. The combination of Banks with Shaw and Maffetone does not provide any teaching of a resiliently deformable projections or pawls. There is nothing in Shaw, Maffetone, or Banks to suggest that it would be obvious to use a pair of resiliently deformable projections to adopt two different positions relative to the pawls to initially block the pawls from engaging the plunger ratchet and subsequently allow the pawls to engage the plunger ratchet only after the plunger depression has started.

Furthermore, the only cited feature that Banks adds to Shaw and Maffetone is the splines 7-10 that lock into guide channels 11 – 14 in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6). The splines in Banks, however, serve a different purpose and function than that set forth in the claimed invention. The spline position of Banks is designed to guide the plunger through the stages of the syringe use. First, the plunger is first

withdrawn to its maximum point “so that shoulders 22 and 23 of the guide channels 12 and 14 no longer prevent clockwise rotation of the plunger.” (*See Banks*, p. 5, lines 23-25). Second, the plunger is then “free to rotate clockwise through ninety degrees . . . in order to disengage the ratchet teeth 15 from pawl 17 in order to allow downward stroke of the plunger.” (*See id.*, p. 6, lines 1-4). “After such ninety degree rotation . . . ratchet teeth 15 are disengaged from pawl 17 but that ratchet teeth 28 on spline 7 are not engaged with pawl 29 and teeth 30 forming the base of guide channel 12 and best viewed in figure 3.” (*See id.*, p. 6, lines 9-12). Thus, Banks teaches a separate guide system for withdrawing the plunger from that which guides the system during the syringe delivery. In contrast, the present invention describes a system where the same fingers 44A, 44B of the outer member 40 slidably engage opposed guide slots 28 on the plunger rod 21 to assure “[a]lignment and non-rotation of the plunger 20,” *see* p. 5, line 10, throughout the withdrawal and delivery steps.

In view of the foregoing remarks, the Office is respectfully requested to reconsider and withdraw the rejection of claims 1, 7, 15, 16, 18, and 24. Since claims 2-6 depend from and contain the limitations of claim 1, claims 8-11, and 13-14 depend from and contain the limitations of claim 7, claims 19-23 depend from and contain the limitations of claim 18, and claims 25-30 depend from and contain the limitations of claim 24, they are distinguishable over the cited references and patentable in the same manner as claims 1, 7, 15, 16, 18, and 24.



In view of all of the foregoing, Applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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